MAY 17 2011

510(k) SUMMARY	
Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614-5686
Contact Person:	Marguerite Thomlinson, JD Sr. Manager, Regulatory Affairs Edwards Lifesciences, LLC, Critical Care Phone: (949) 756-4386 Fax: (949) 809-5676
Date Prepared:	April 18, 2011
Trade Name:	Vigileo Arterial Pressure Cardiac Output (APCO)/Oximetry Monitor
Common Name:	Cardiac Output/Oximeter Computer
Classification Name:	Single-Function, Preprogrammed Diagnostic Computer (21 CFR 870.1435)
Regulation Class/ Product Code	Class II/ DXG, DQE
Predicate Devices:	K082308, Edwards Lifesciences LLC, Vigileo Arterial Pressure Cardiac Output/Oximetry Monitor
Device Description:	The Vigileo Arterial Pressure Cardiac Output (APCO)/Oximetry Monitor (Vigileo Monitor) is a microprocessor-based instrument. When used with the FloTrac sensor, the Vigileo Monitor continuously measures key parameters of arterial pressure cardiac output (CO), cardiac index (CI), oxygen delivery (DO_2), oxygen delivery index (DO_2I), stroke volume (SV), stroke volume variation (SVV), stroke volume index (SVI), systemic vascular resistance (SVR) and systemic vascular resistance index (SVRI). When used with Edwards oximetry catheters, the Vigileo Monitor measures central venous oxygen saturation ($ScvO_2$) and mixed venous oxygen saturation (SvO_2). The instrument software has been revised to enhance the SVV algorithm, improve the GUI and add compatibility with additional external devices for data output.

510(k) SUMMARY	
Indications for Use/ Intended Use	The Vigileo APCO/Oximetry Monitor is indicated for continuously measuring hemodynamic parameters such as cardiac output and oximetry to assess oxygen delivery and consumption. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics. The monitor also displays parameters, such as stroke volume and stroke volume variation, used to assess fluid status and vascular resistance. The Vigileo APCO/Oximetry Monitor may be used in all setting in which critical care is provided.
Comparative Analysis:	Verification and validation testing was conducted to compare the performance and functionality of the pending and the predicate devices. This testing regimen included side-by-side bench and pre-clinical studies, and comparative analysis of clinical data. The Vigileo Monitor has been shown to be safe and effective and substantially equivalent to the cited predicate device for its intended use in the OR and ICU environments.
Functional/ Safety Testing:	The Vigileo Monitor has successfully undergone functional and performance testing, including software verification and validation, mechanical and electrical testing, bench studies, pre-clinical animal studies, comparison testing of clinical cases, and clinical usability. The Vigileo Monitor has been shown to be safe and effective and substantially equivalent to the cited predicate devices for their intended use in the OR and ICU environments.
Conclusion:	The proposed Vigileo Monitor is safe and effective and is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Edwards Lifesciences
c/o Ms. Marguerite Thomlinson
Sr. Manager of Regulatory Affairs, Critical Care
One Edwards Way
Irvine, CA 92614

MAY 17 2011

Re: K103094
Trade/Device Name: Vigileo Arterial Pressure Cardiac Output/Oximetry monitor
Regulation Number: 21 CFR 870.1435
Regulation Name: Single-Function, Preprogrammed Diagnostic Computer
Regulatory Class: Class II (two)
Product Code: DXG, DQE
Dated: April 18, 2011
Received: April 21, 2011

Dear Ms. Thomlinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): [redacted] K103094

Device Name: Vigileo APCO/Oximetry Monitor

Indications For Use:

The Vigileo APCO/Oximetry Monitor is indicated for continuously measuring hemodynamic parameters such as cardiac output and oximetry to assess oxygen delivery and consumption. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics. The monitor also displays parameters, such as stroke volume and stroke volume variation, used to assess fluid status and vascular resistance. The Vigileo APCO/Oximetry Monitor may be used in all setting in which critical care is provided.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109 Subpart D) (Per 21 CFR 801.109 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[redacted]

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K103094